PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| Applicant's or agent's file reference 31978-206599 | FOR FURTHER ACTION | See item 4 below | |
|--|--------------------|------------------|--|
| International application No. International filing date (day/month/year) PCT/US2004/029293 International filing date (day/month/year) O8 September 2004 (08.09.2004) Priority date (day/month/year) O8 September 2003 (08.09.2003) | | | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | | |
| Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA, ASrepresented by THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES | | | |

| 1. | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the |
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| | International Searching Authority under Rule 44 bis. 1(a). |

2. This REPORT consists of a total of 22 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

| X 1 | Box No. I | Basis of the report |
|-------------|--------------|---|
| | Box No. II | Priority |
| | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| | Box No. IV | Lack of unity of invention |
| | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| \boxtimes | Box No. VI | Certain documents cited |
| X I | Box No. VII | Certain defects in the international application |
| X I | Box No. VIII | Certain observations on the international application |
| | | |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

| | Date of issuance of this report 13 March 2006 (13.03.2006) |
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